K003398

SPECIAL 510(k) Notification
WireClip™ torquer

DEC - 1 2000

Section 4. Summary of Safety and Effectiveness

(Pursuant To Section 12 of the SAFE MEDICAL DEVICES ACT of 1990)

General Provisions	Submitter's Name and Address	Boston Scientific Corporation Northwest Technology Center, Inc. 17425 N.E. Union Hill Road Redmond, WA 98052
	Contact Person	Jocelyn Kersten Regulatory Affairs Project Manager 425-556-1667 425-558-1400 (fax)
	Classification Name	Not known
	Classification	Class II
	Common or Usual Name	Guide wire torquer
	Proprietary Name	wireClip torquer

Name of Predicate Devices	Predicate Device	510(k) Reference No.
	Heart Technology wireClip	K914581

SPECIAL 510(k) Notification
WireClip™ torquer

Device Description	The wireClip torquer is a plastic device that attaches to guide wires which have shaft diameters from 0.009 inches to 0.018 inches (0.23 mm to 0.46mm). The wireClip torquer is a side mounted device. When the handles located on one side of the wireClip are squeezed, the groove in the wireClip opens, allowing the guide wire to be placed inside. Releasing the handles allows the groove to close, capturing and firmly gripping the guide wire. A line drawing of the wireClip is provided in Appendix A.
Intended Use	The wireClip torquer is intended to allow the user to securely hold the guide wire during manipulation of the guide wire and operation of the Rotablator advancer/catheter.
Summary of Technological Characteristics	The proposed holding force specification change does not result in any technology changes.
Test Summary	The wireClip itself is unchanged. Testing has confirmed the revised holding force is adequate for the intended use of the wireClip and the wireClip meets the revised specification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 1 2000

Ms. Jocelyn Kersten
Regulatory Affairs Project Manager
Boston Scientific Corporation
Northwest Technology Center, Inc.
17425 N.E. Union Hill Road
Redmond, WA 98052-3376

Re: K003398
Trade Name: wireClip™ Torquer
Regulatory Class: II (two)
Product Code: DQX
Dated: October 26, 2000
Received: November 1, 2000

Dear Ms. Kersten:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 3. Indication for Use

510(k) Number K003398

Device Name wireClip torquer

Indications for Use The wireClip torquer provides a convenient gripping surface for manipulating steerable guide wires. The wireClip torquer may also be used as an adjustable stop to limit the advancement of the steerable guide wire within angioplasty catheters.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over The Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003398